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Your reference: VS:VM:P33664

Examiner's first report on patent application no.41323/97
by Elizabeth SHANAHAN-PRENDERGAST

Dear Ms. Santer,

I am replying to the request for examination. I have based this report on the pamphlet and the amendments already made under the Articles of the PCT dated 23 January 1998. I have examined the application and believe that the following objections apply:

1. There is no Notice of Entitlement on file.
2. The specification does not fully describe the invention. Many aspects of the invention are described. It is not clear what combination of features described in these aspects represent the inventive concept.

When I consider all of the claims together, I cannot understand the scope of the monopoly being claimed because it is not readily clear what combination of integers defines the invention or what the unifying concept is. This is because different claims have different combinations of integers.

Furthermore the claims are not fairly based because each of the independent claims do not include all of the features of the various aspects which are stated as characterising the invention in the description. Each independent claim must define all the essential features of the invention.

3. The specification does not comply with Section 40(4), as the claims do not relate to one invention only. In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to be essential technical features and which potentially distinguish the claimed invention from the prior art. Where different claims have a different set of essential features, they define different inventions. I have found that there are eight different inventions as follows:

- (1) Claims 1-5 define the administration of venom and PLA₂ anti-serum to treat neoplasm;
- (2) Claims 6 and 7 define formulations comprising venom and PLA₂ anti-serum and PLAC;
- (3) Claims 8 and 9 define formulations and methods of use of same to treat neoplasm, where the formulations comprise venom and PLA₂ and PLAC;
- (4) Claims 26-31 define methods of inoculation with two or more PLA₂;
- (5) Claims 33 and 34 define the detection of neoplasm by detecting high PLA₂ levels;
- (6) Claim 36 defines the targeting of cancer cells by using PLA₂ as targeting agent;

- (7) Claim 37 defines the targeting of cancer cells by using liposomes containing PLA₂ anti-serum or virtually any chemotherapeutic drug;
- (8) Claims 38-42 define the administration of venom and PLA₂ anti-serum to treat parasitic or bacterial infections.

Since the above-mentioned groups of claims do not share a common set of essential features, a technical relationship between these eight inventions does not exist. Thus, the claims do not relate to one invention. Please note also that examination of fair basis is necessarily reserved pending resolution of objection 3.

4. Claims 33 and 34 are not clear as they purport to define a method of detecting a disease, but fail to give any method steps by which that method may be performed. It is not clear how the method should be performed of what method steps were intended to be claimed.

5. Claim 37 is not clear because:

(i) its appendence to claim 36 is not clear. I note that claims 36 and 37 define distinct inventions (as outlined at objection 3). Claim 36 defines the use of PLA₂ *per se* whereas claim 37 defines the use of anti-serum to PLA₂ or the use of any known "conventional chemotherapy drugs". It is not clear therefore how claim 37 could be appended to claim 36;

(ii) the words "or conventional chemotherapy drugs" introduce a lack of clarity as it is not clear what drugs were envisaged by the applicant. As a consequence of those words, claim 37 may be construed to define a method that uses a liposome containing any chemotherapeutic agent. This would render the claim not clear and not fairly based on the description.

6. Claims 33-36 are not novel in the light of EP document number 0459450 by Shionogi Seiyaku KK, published on the 4th of December 1991. This document discloses methods of detecting cancers (neoplasms) and methods of targeting PLA₂ with PLA₂ anti-sera and/or with immuno-assays that use those PLA₂ anti-sera.

You have 21 months from the date of this report to overcome my objections. However, if you file your response after 12 months from the date of this report a response fee is payable.

Yours sincerely,



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